REMARKS

This paper responds to the non-final office action of May 11, 2006. Claims 43, 44, 46-47, 49, 50, 52, 54, 55, 57-58, and 59-61 are pending. Claims 59-63 are new. Of the existing claims, all but claim 47 are rejected as anticipated by U.S. Patent 6,027,499 to Johnston et al., while claim 47 is rejected as obvious over Johnston et al. in view of U.S. Patent 6,355,029 to Joye et al.

The Applicant discusses below why each pending claim is in condition for immediate allowance, and respectfully requests that the pending claims be allowed to issue.

Rejections Pursuant to 35 U.S.C. § 102 over Johnston et al.

Claims 43, 44, 46-47, 49, 50, 52, 54, 55, and 57-58 stand rejected under 35 U.S.C. § 102(e) as being anticipated by the Johnston et al. patent. Claims 43, 52, and 55 are the independent claims of this group. Claim 43 as amended recites a device having a cryo therapy apparatus that is sized and arranged for vascular introduction, and an optical sensor to monitor temperatures created by use of the cryo therapy apparatus. Claim 52 as amended recites a device having a cryo therapy apparatus sized and arranged for vascular introduction, and an optical imaging apparatus to monitor temperatures resulting from use of the cryo therapy apparatus. Claim 55 as amended recites a method of monitoring the temperature of a vascular area during a cryoplasty procedure by providing a temperature monitoring device including a cryo therapy apparatus and an optical sensor in a vascular system, cooling the vascular area, and measuring temperature.

The Johnston patent, in great contrast, is directed toward cryogenic spray ablation of the gastrointestinal mucosa to treat Barrett's esophogous. In the Johnston process, cryogenic fluid is sprayed onto the walls of the esophogous while a physician visually monitors the procedure using a camera with optical fibers to extend the reach of the camera into the esophogous. *See* Johnston, Abstract; Fig. 1.

Thus, Johnston's system and method differ from the pending claims in numerous ways. For example, the Johnston system does not contain a temperature sensor of any sort. Rather, it has only a camera that generates an image, but does nothing to sense a temperature. While a physician can look at a television to determine whether tissue has frozen, that is entirely and fundamentally different from providing an actual temperature sensor at the distal end of the device, so as to obtain a real reading regarding temperature. Moreover, the optical fiber in Johnston is entirely separate from the cooling device, and thus does not meet the feature of pending claims 43 and 52 that the sensor be part of the same device as the cryo therapy apparatus.

Also, claims 43 and 52, as amended, recite that the cryo therapy device or apparatus be sized and arranged for vascular introduction. Claim 55 as amended recites a process that takes place in a vascular area. A patient's vasculature is extremely restricted in size and path, and thus requires an apparatus that is very small in cross-section and can be manipulated carefully to a target site. The Johnston device, in contrast, is made for the esophagus, a much larger and easier-to-navigate passage. The Johnston device has a relatively large catheter (20) and a separate nasogastric tube (41). Thus, the Johnston patent does not meet this feature of the claims and Applicant submits that the claims are in condition for immediate allowance.

The difference between the pending claims and Johnston is not simply an obvious change of reduced size. Rather, the Johnston device has a number of features that prevent its reduction in size or its use in a more confined setting than the esophagus. For example, the balloon (43) in Johnston depends on gravity to pull it downward toward the stomach, and thus would not extend properly if in a very tight passage and a non-vertical orientation. Also, the Johnston system requires multiple different devices, such as a catheter separate from an optical fiber, and would thus be difficult to coordinate and guide in a restricted area. And the particular arrangement of items in the catheter make for a relatively large device. Moreover, while a camera may provide a good image in a relatively large, straight, and unfilled passage like an esophagus, it would have little to no applicability in a narrow, bending passage that is partially or wholly filled with fluid like blood. Nor does the Johnston patent suggest in any location that the catheter would be

flexible in any manner. Thus, the Johnston device would be inappropriate for modification to meet the features of the pending claims, there is no motivation to modify the Johnston device so as to meet those features, and the Johnston patent actually teaches away from such modification. Applicant thus respectfully requests allowance of these independent claims, and the claims that depend on them.

Rejections under 35 U.S.C. § 103 over Johnston in view of Joye et al.

The Examiner rejected claim 47 under 35 U.S.C. § 103 over Johnston in view of Joye et al. (U.S. Pat. 6,355,029).

These claim depends directly on independent claim 43 discussed above. For the reasons discussed above, the Johnston patent neither discloses nor fairly suggests the inventions recited in claim 47. The Office Action also does not rely on Joye as disclosing all of the features of any of the claim, and Applicant submits that Joye does not correct the defects discussed above for Johnston. As a result, Applicant respectfully submits that claim 47 is patentable.

New Claims

New claims 59-63 all depend on claim 43. Support for the claims may be found throughout the specification as originally filed. In particular, support for claim 59 may be found, for example, in the original application at page 3, lines 15-19; page 11, lines 7-12. Support for claim 60 may be found, for example, at page 6, line 19 to page 7, line 6, and page 7, lines 22-23. Support for claims 61 and 62 may be found, for example, at page 5, line 11 to page 6, line 2, and in figures 3-8.

The new claims are patentable for all of the reasons discussed above for claim 43, on which they depend. In addition, claim 59 recites that the optical sensor is an infrared optical sensor. Nothing in either reference applied by the Office discloses or suggests such a feature. In particular, an infrared sensor provides for the ability to sense activity invisible to the human eye, while Johnston's fiber optic camera is limited to visual changes in the esophageal mucosa. Claim 60 recites the additional feature of a fluorescing marker band positioned to permit

locating the device during an internal medical procedure. Johnston neither discloses nor suggests such a feature, and would have no need for such a feature because the system in Johnston is guided visually using a camera. Claim 61 recites a temperature sensor that includes a detector in predetermined positional relationship to an emitter. Johnston, of course, includes no such structure or arrangement of structures, nor does it suggest the use or arrangement of such structures.

Claims 62 and 63 (which depends on claim 62) are particularly distinguishable from Johnston. Claim 62 recites that the cryo therapy apparatus comprises an expandable balloon defining an interior volume in fluid communication with a coolant supply lumen. Thus, the expanding balloon itself carries the cooling fluid, and causes the cooling. Such an arrangement is plainly taught away from in Johnston, as Johnston warns that such an arrangement—i.e., of putting fluid into physical structure rather than spraying it into the body cavity—is problematic because it can cause various problems in cooling tissue. Johnston patent, Col. 1, line 66 – Col. 2, line 20. Thus, Johnston plainly teaches away from such features. Applicant thus respectfully submits that each of the new claims is patentable even if the rejections of the other claims are continued.

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Respectfully submitted,

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